WO 2005/039487 PCT/US2004/029902

- 18 -

## **CLAIMS**

- 1. A method for detection of ovarian cancer in an individual who has not been diagnosed with ovarian cancer and who is not displaying symptoms associated with stage III or IV ovarian cancer, comprising the steps of
  - (a) obtaining a sample from the individual;
  - (b) determining the amount of expressed YKL-40 in the sample; and
- (c) comparing the amount of expressed YKL-40 determined to a pre-determined threshold, wherein if the predetermined threshold is exceeded, the test is deemed to be an indicator of ovarian cancer in the individual.
  - 2. The method of claim 1, wherein the sample is a serum or plasma sample.
- 3. The method of claim 2, wherein the pre-determined threshold is at least two standard deviations higher than the mean amount of YKL-40 detected in a population of individuals who do not have ovarian cancer.
- 4. The method of claim 3, wherein the population of individuals is composed of individuals within an age group range of which the individual tested is a member.
- 5. The method of claim 3, wherein the population of individuals consists of individuals who themselves have increased risk factors for ovarian cancer.
- 6. The method of claim 1, wherein the pre-determined threshold is at least two standard deviations higher than the mean amount of YKL-40 detected in a population of individuals who do not have ovarian cancer.
- 7. The method of claim 6, wherein the population of individuals is composed of individuals within an age group range of which the individual tested is a member.

WO 2005/039487 PCT/US2004/029902

- 19 -

- 8. The method of claim 6, wherein the population of individuals consists of individuals who themselves have increased risk factors for ovarian cancer.
- 9. The method of claim 1, wherein the amount of YKL-40 is determined using an immunoassay.
- 10. The method of claim 1, further comprising the step of testing the sample for the amount of CA-125 and taking both the measured amount of YKL-40 and the measured amount of CA-125 into consideration in determining the presence of ovarian cancer.
- 11. A method for assessing the risk of post-treatment recurrence in a patient diagnosed with early stage ovarian cancer comprising the steps of
  - (a) obtaining a pre-operative sample from the individual and
- (b) determining the amount of expressed YKL-40 in the sample; wherein a preoperative level of greater than 80 ng/mL is indicative of an increased risk of post-treatment recurrence of ovarian cancer.
  - 12. The method of claim 11, wherein the sample is a serum or plasma sample.
- 13. The method of claim 12, wherein the amount of YKL-40 is determined using an immunoassay.
- 14. The method of claim 11, wherein the amount of YKL-40 is determined using an immunoassay.
- 15. Use of reagents for the quantitative determination of YKL-40 in a sample for detection of ovarian cancer in an individual who has not been diagnosed with ovarian cancer.
- 16. Use of reagents for the quantitative determination of YKL-40 in a sample for assessing the risk of post-treatment recurrence in a patient diagnosed with early stage ovarian cancer.